Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

The claims in the application at the time of issuance of the Office Action were claims 1-9, 11, 24, 26, 30 and 31.

Claims 5-9, 11, 24 and 26 have now been cancelled.

Claim 1 has been amended as indicated. Support for these amendments is apparent from the specification as a whole, and more particularly, page 18 lines 8-28 and page 24, lines 8-18.

Other claims have been amended to be consistent with the amendments to claim 1.

The patentability of the presently claimed invention, after entry of the foregoing amendments, over the disclosures of the references relied upon by the Examiner in rejecting the claims, will be apparent upon consideration of the following remarks.

Present Invention

The claims have been amended to reflect the following characteristics of the biologically active polymer product according to the present invention.

(i) The polymer substrate has grafted chains having functional groups. The functional groups on the grafted chains may function as "active sites" to immobilize the biologically active compound moiety. Please refer to, for example, page 24, lines 8-18 and page 25, lines 12-23 of the specification.

(ii) The biologically active compound moiety is covalently bonded to the grafted chain via the functional group. Please refer to, for example, page 24, line 19 to page 25, line 2 of the specification.

(iii) The grafted chains are introduced onto the polymer substrate by radiation-induced graft polymerization. This is reflected by the wording in claim 1 "wherein said polymer substrate . . . is produced by irradiating a polymer substrate with radiation, and then exposing . . .".

The radiation-induced graft polymerization may be classified into two types, that is, a pre-irradiation process in which the substrate is first irradiated and then brought into contact with a graft-forming monomer, and a simultaneous irradiation process in which the substrate is irradiated

in the presence of a graft-forming monomer. By the above-mentioned wording in claim 1, it is clarified that the grafted chain is formed by "pre-irradiation" graft polymerization.

(iv) The biologically active compound moiety carried on the polymer substrate through the functional group on the grafted chain is limited to specific antibiotics, which are described in page 18, lines 8-28 of the specification.

In the present invention, grafted chains are formed by a "pre-irradiation type radiation-induced graft polymerization method" (the above characteristic (iii)). According to this method, radicals are formed not only on the surface of the polymer substrate but also deep inside the substrate. Accordingly, graft chains also are formed not only on the surface of the polymer substrate but also deep inside the substrate.

According to the other characteristics of the present invention, a specific biologically active moiety is bonded to the grafted chain via a functional group. The biologically active moieties listed in amended claim 1 are all antibiotics of the type having a macromolecular structure such as fused rings or macrocyclic ring structure (above-mentioned characteristic (iv)). Such a macromolecule compound cannot penetrate deep inside the substrate due to its sterically bulky structure. Thus, the biologically active moiety is mainly bonded to the functional group on the grafted chain formed on the surface of the substrate. Accordingly, the polymer product of the present invention has grafted chains having the biologically active moiety on the surface of the substrate and also grafted chains having a functional group retained as it is in the inside of the substrate.

When the biologically active polymer product of the present invention is used, functional groups on the grafted chains inside the substrate adsorb some water molecules around them, by which interspaces between the grafted chains are expanded. This phenomenon is called in the art "expansion of grafted chains". By this phenomenon, grafted chains formed on the surface of the substrate become more movable, that is, mobility of the grafted chains formed on the surface of the substrate is achieved, and accordingly mobility of the biologically active moiety bonded to the grafted chains becomes higher. Antibiotics function to attack microorganisms and the like by contact of predefined functional groups on the sterically bulky molecule of the antibiotics with a predefined site of the microorganism. By using the biologically active polymer product of the present invention, antibiotics

bonded to the grafted chains will move in a swimming manner due to their high mobility, so that contact efficiency between the predefined functional groups on the molecule of the antibiotics and the predefined sites of the microorganism is high. Accordingly, very high biological activity is obtained in the biologically active polymer product of the present invention.

Further, the functional group retained as it is inside the substrate functions to improve affinity of the polymer product of the present invention to the hydrophilic moieties present in the outermost surface of the microorganism. This also improves biological activity of the polymer product of the present invention.

The Rejections

The rejection of claims 1-7, 11, 24 and 26 under 35 U.S.C. §102(b) as being anticipated by Guire, as applied to the amended claims, is respectfully traversed.

The method of Guire is photo-initiated graft polymerization, by which radicals are formed only on the surface of the substrate and not inside the substrate. Thus, the material of Guire does not have grafted chains inside the substrate, which contribute mobility of grafted chains by means of adsorbed water molecules. Therefore, in the material of Guire, a biocompatible agent moiety bonded to the surface of the substrate has less mobility than the material of the present invention, which results in less contact with microorganisms, and accordingly the material of Guire has less bioactivity than the material of the present invention. Guire does not teach or suggest the technical concept and constitution of the present invention as explained above.

The rejection of claims 1-6, 11, 24 and 26 under 35 U.S.C. §102(b) as being anticipated by Patnaik et al. '165 is respectfully traversed.

Patnaik et al. disclose a medical device comprising a polymer substrate having a bio-active coating bound to the surface thereof, but do not teach or suggest the use of radiation-induced graft polymerization. Thus, the material of this reference does not have grafted chains inside the substrate; and the reference does not teach or suggest the technical concept and constitution of the present invention as explained above.

The rejection of claims 8-9 under 35 U.S.C. §103(a) as being unpatentable over Guire, as well as the rejection of claims 6-9 under 35 U.S.C. §103(a) as being unpatentable over Patnaik et al. '165, have been rendered moot in view of the cancellation of these claims.

The rejection of claims 1-6, 11, 30 and 31 under 35 U.S.C. §102(b) as being anticipated by Sugo, as applied to the remaining claims, is respectfully traversed.

Sugo discloses radiation-induced graft polymerization and also teaches pre-irradiation type graft polymerization. The main difference between the present invention and Sugo is the structure of the biologically active compound moiety bonded onto the functional group on the grafted chains. Sugo discloses the use of compounds having a considerably small molecular structure, such as hydroxylamine (Example 1), glycine (Example 2), and phenylalanine (Example 3). Since these compounds have a considerably small molecular structure, they easily penetrate deep inside the substrate. Thus, the antimicrobial materials of Sugo have grafted chains having an active compound moiety on the surface of the substrate as well as inside of the substrate. Therefore, even when the antimicrobial material of Sugo is placed in an environment for use, expansion of grafted chains due to adsorption of water molecules around the functional groups on the grafted chains does not occur. As the active compound moiety of Sugo is considerably small and very simple functional groups such as an amino group or imino group carry out the bioactive function, the bioactive mechanism in Sugo's material is quite different from the material of the present invention which provides bioactivity by the contact of predefined functional groups on the sterically bulky molecule of the antibiotics with a predefined site of the microorganism. Therefore, high mobility of the active compound moiety for intimate contact between the active compound moiety with a microorganism is not necessary in Sugo's material. Sugo does not teach or suggest the technical concept and constitution of the present invention as explained above.

The rejection of claims 1-7, 9, 11 and 30 under 35 U.S.C. §102(b) as being anticipated by Goldberg et al. is respectfully traversed.

The method of Goldberg et al. is so-called simultaneously irradiation type radiation-induced graft polymerization in which a substrate is irradiated in the presence of graft-forming monomer, for example, a substrate impregnated with graft-forming monomer is irradiated. By this method,

formation and growing of graft chains on the substrate as well as polymerization of the monomer itself proceed simultaneously. Thus, as the graft polymerization reaction proceeds, a graft-forming moiety to be attached onto the substrate becomes bigger due to its self-polymerization, which is difficult to penetrate deep inside the substrate. Accordingly, the grafted material made by the method of Goldberg et al. has less grafted chains inside the substrate than the material of the present invention. Thus, similarly to Guire, in the material of Goldberg et al., functional groups on the grafted chains bonded to the surface of the substrate have less mobility than the material of the present invention. Furthermore, Goldberg et al. do not teach or suggest that an antibiotic is bonded to the grafted chains.

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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